

REMARKS

Claims 1-2, and 4-13 were pending in the application. Claims 10, 12, and 13 have been previously withdrawn from consideration. Claim 3 has been previously cancelled

The Examiner objected to claim 9 because element 9c of the claims 5 to 810% of a surfactant or surfactant mixture in the composition. This is a typographical error and has been replaced with 80% which is claimed in previous claim 9.

The Examiner has rejected claims 1-2, 4 and 6 under 35 U.S.C. § 102(b) as being anticipated by Weder et al. (EP 733373 A2) or under 35 U.S.C. § 102(e) as being anticipated by Weder et al. (US 5726164 A). Claims 1-2, 4 and 6 have been herein cancelled thus rendering this rejection moot. The Applicants respectfully request that the Examiner withdraw the rejection based on these grounds.

The Applicants have amended claim 11 to more distinctly point out the patentable novelty and non-obvious nature of the Applicants' invention. Support for the amendment to claim 11 may be found in previous claim 11 and also in the Specification on page 1 in lines 18-21.

The Examiner has rejected claims 9 and 11 under 35 U.S.C. § 103(a) over Weder et al. (EP 733372 or its equivalent US 5726164). The Examiner states that one of ordinary skill would have readily optimized effective dosages as determined by good medical practice. The Applicants respectfully disagree with the Examiner and request that the rejection be withdrawn.

The Applicants have not merely chosen a dosage which provides a certain bioavailability but have created a composition which is significantly bioavailable and which could not be predicted or suggested from a reading of the compositions which are taught in Weder et al. Weder et al. teach an injectable formulation which does not present the problems of bioavailability of an orally administered composition such as the Applicants. The bioavailability of an injected active ingredient in any type of composition is assumed to be 100% since it is entirely administered into the blood of a subject. There are organ system pass-through effects and problems of complete absorption associated with an orally administered active ingredient, particularly when the active ingredient is poorly soluble in an aqueous environment, such as n-benzoyl-staurosporine, which prevent complete absorption of an active ingredient which is orally administered to a subject. Thus, drawing comparisons of the bioavailability of an injectable composition, or the teachings of an injectable composition such as described in Weder et al., to

that of the Applicants' orally administered composition invention are wholly irrelevant and are run against pharmacological practice. There is no suggestion that one could gain from the teachings of an injectable form, such as that of Weder et al., that would lead one to design an oral form, such as that of the Applicants' invention. Therefore, the Applicants assert that from a reading of Weder et al. one skilled in the art would not be motivated to create the Applicants' present invention. Therefore, the Applicants respectfully request that the Examiner withdraw the rejection based on 35 U.S.C. § 103(a) over Weder et al.

The Examiner has rejected claims 5, 7, and 8 under 35 U.S.C. § 103(a) over Weder et al. (EP 733372 or its equivalent US 5726164) in view of Henry (US 5736542) and Weder et al. (US 5658898). Claims 5, 7, and 8 have been herein cancelled thus rendering this rejection moot. The Applicants respectfully request that the Examiner withdraw the rejection based on these grounds.

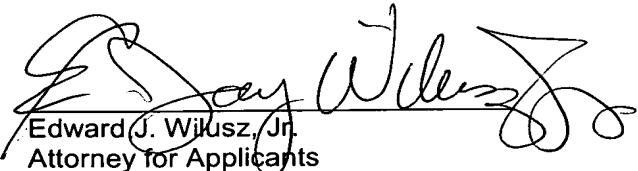
The Applicants believe that the Application is now in condition for allowance and request early notice to that effect.

The Examiner is herein authorized to charge Deposit Account No. 19-0134 in the name of Novartis Corporation for fees which may be properly assessable in the case and to refund fees paid in excess of amounts owed.

If it will advance prosecution of the Application the Examiner is urged to contact the Applicants' undersigned counsel at the telephone number listed below.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7960


Edward J. Wilusz, Jr.
Attorney for Applicants
Reg. No. 52,370

Date: *26 January 2005*